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DEPARTMENT OF STATE

Public Notice: 9495

Request for Comments on World Health Organization Pandemic Influenza Preparedness Framework Review

AGENCY: International Health and Biodefense, U.S. Department of State

ACTION: Notice and Request for Comments.

SUMMARY: The U.S. Department of State invites submission of comments from the public and relevant industries on influenza surveillance and response, related to the implementation of the World Health Organization (WHO) Pandemic Influenza Preparedness Framework (PIP-FW)

(http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_8-en.pdf). Comments are specifically requested on the PIP-FW Review areas of virus sharing and benefits sharing, and on governance and linkages with other international programs or instruments.

DATES: Written comments on PIP-FW virus sharing and benefits sharing must be submitted on or before April 10, 2016, and written comments on PIP-FW governance and linkages must be submitted before May 25, 2016. Comments should be no more than 15 pages with single spaced text.

ADDRESSES: Submissions should be made via the Internet at www.regulations.gov docket number DOS-2016-0016. For alternatives to online submissions please contact Bruce Ruscio at (202) 647-3017 or ruscioba@state.gov. Note that relevant comments submitted to regulations.gov will be posted without editing and will be available to the

public; therefore, business-confidential information should be clearly identified as such and submitted by e-mail. The public is strongly encouraged to file submissions electronically rather than by facsimile or mail.

FOR FURTHER INFORMATION, PLEASE CONTACT: Questions regarding the submission of comments should be directed to Bruce Ruscio (202) 647-3017, ruscioba@state.gov, or Robert Sorenson at (202) 647 4689, sorensonra@state.gov.

SUPPLEMENTARY INFORMATION:

In 2007, the Sixtieth World Health Assembly passed a resolution calling on the Director-General to convene an intergovernmental meeting to develop mechanisms to ensure the continued sharing of potential pandemic influenza viruses, and the fair and equitable sharing of benefits arising from such sample sharing. For four years, WHO member states met as an Intergovernmental Mechanism, as well as informally, to negotiate the Pandemic Influenza Preparedness Framework (PIP-FW). The PIP-FW came into effect on May 24, 2011 when it was unanimously adopted by the Sixty-fourth World Health Assembly. At the core of the PIP-FW is a robust Global Influenza Surveillance and Response System (GISRS, previously called the Global Influenza Surveillance Network or GISN).

The key goals of the PIP-FW are to improve and strengthen global influenza pandemic preparedness by:

- 1) Ensuring the global sharing of influenza viruses with human pandemic potential for continuous global monitoring and assessment of risks, and for the

development of safe and effective countermeasures. The PIP-FW provides a transparent mechanism for sharing virus samples, based on two Standard Material Transfer Agreements (SMTAs) that specify the conditions for samples passed within and outside of the GISRS, and a traceability mechanism to monitor the movement of samples.

2) Increasing countries' access to vaccines and other pandemic related resources. Two innovative and complementary benefit-sharing mechanisms pool monetary and in-kind contributions from entities that use the GISRS to enhance pandemic influenza preparedness and response capacity for countries in need and at risk of pandemic influenza: the annual partnership contribution and the SMTA-2.

Section 7.4.2 of the PIP-FW provides that: “The Framework and its Annexes will be reviewed by 2016 with a view to proposing revisions reflecting development as appropriate, to the World Health Assembly in 2017, through the Executive Board.” It is in anticipation of the 2016 review that the U.S. Department of State seeks comments on the following points:

- 1) Perspectives on the PIP-FW efforts in advancing global pandemic influenza preparedness, including inter-pandemic surveillance, and capacity to respond.
- 2) Experiences relating to the status and process of concluding Standard Material Transfer Agreements (SMTA-2).
- 3) Use of partnership contributions and WHO efforts to strengthen the GISRS and overall global preparedness and response capability/capacity.

- 4) How changing technology has impacted or has the ability to impact the existing PIP-FW, specifically as regards genetic sequence data.
- 5) Potential linkages with other instruments, including the Nagoya Protocol.
- 6) Other matters related to prevention, planning and response whose resolution will be integral for the effective operation of a global influenza pandemic response.

The facts and information obtained from written submissions will be used to inform the participation of the U.S. Department of State in the interagency process to prepare for United States participation for the five-year 2016 review of the PIP-FW. Upon receipt of the written submission, representatives from the Department of State will consider them and share them, as appropriate, with other interested U.S. Government agencies and departments engaging in the five-year review process.

The Department of State invites comments from civil society organizations as well as pharmaceutical and medical technology industries and other interested members of the public. Entities making submissions may be contacted for further information or explanation.

Two meetings are planned in association with this request for written submissions.

Time and Date: The meetings will begin at 2:00 p.m. EDT on Monday, May 2, 2016, and Thursday, June 16, 2016. Both meetings will continue until 4:30 p.m.

each day.

Place: Both meetings will be held at the US State Department's Harry S. Truman Building, 2201 C Street, NW, Washington, DC 20520. Please use the 23rd Street entrance, and plan to arrive at least _twenty_ minutes prior to the start of the meeting to allow for ID verification and escorting requirements.

Status: The meeting will be open to the public. Persons planning on attending must provide their full name and organization to Dr. Bruce Ruscio at ruscioba@state.gov three days prior to each meeting. Persons who need special accommodations should also contact Dr. Ruscio at ruscioba@state.gov or (202) 647-3017 seven days before each meeting. Requests made after that time will be considered, but might not be possible to accommodate.

Personal data is requested pursuant to Pub.L. 99-399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Pub.L. 107-56 (USA PATRIOT Act); and E.O. 13356. The purpose of the collection is to validate the identity of individuals who enter 5 Department facilities. The data will be entered into the Visitor Access Control System (VACS-D) database. Please see the Security Records System of Records Notice (State-36) at <https://foia.state.gov/docs/SORN/State-36.pdf> for additional information.

Dated: March 24, 2016

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